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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/684,025	10/10/2003	Marc S. Collett	1282-P00645US3	3173

110 7590 11/12/2004

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PHILADELPHIA, PA 19103-2307

EXAMINER

HORLICK, KENNETH R

ART UNIT	PAPER NUMBER
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1637

DATE MAILED: 11/12/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

10/684,025

**Applicant(s)**

COLLETT ET AL.

**Examiner**

Kenneth R Horlick

**Art Unit**

1637

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 15-22 is/are allowed.
- 6) ☒ Claim(s) 1-14 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 10 October 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_.

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1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Houghton et al. (US 5,371,017) in view of Suzich et al. (1993).

These claims are drawn to recombinantly-produced native, authentic, enzymatically active NTPase/RNA helicase of hepatitis C virus (HCV), said enzyme comprising amino acids 1027-1657 of the HCV NS3 gene product; and to a recombinant method of producing said enzyme.

Houghton et al. disclose recombinant expression of the HCV NS3 gene product, including the entire coding region, fusion proteins, and truncated and altered versions of said gene product (see column 2, lines 5-9). In lines 18-55 of column 4, a "DNA construct encoding the entire NS3 domain" is specifically taught. Columns 7-10 disclose various well-established recombinant expression means in the art, including both expression of fusion proteins and nonfused (native) proteins (see especially column 10, lines 6-16). While specific examples of fusion proteins are disclosed in this patent, the teachings as a whole clearly cover recombinant expression of the full length, native NS3 gene product.

Houghton et al. do not specifically disclose an HCV NS3 gene product comprising amino acids 1027-1657.

Suzich et al. teach that the entire HCV NS3 gene product was known to reside in amino acids 1027-1657 of the HCV polyprotein (see Fig. 1A on page 6153).

One of ordinary skill in the art would have been motivated to apply the teachings of full-length, native recombinant expression of HCV NS3 (Houghton et al.) to an enzyme comprising amino acids 1027-1657 because Suzich et al. taught that these amino acids defined the HCV NS3 gene product. It would have been prima facie obvious to one of ordinary skill in the art at the time of the invention to produce and use the claimed HCV NS3 proteins.

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2. In parent application 10/010,860, the arguments of the response filed 01/30/03 with respect to the instant claims have been fully considered, but are not found persuasive. On page 3 of the response, it is argued that the combined references do not teach or suggest: expression in a eukaryotic expression system; the protein comprising amino acids 1027-1657; and purification such that enzymatic activity is maintained. However, each of these limitations is clearly present in the cited prior art as specifically pointed to in the rejection; the response merely refers to certain different embodiments in the references while ignoring the broader teachings pointed out in the rejection. While the response notes on page 4 that the prior art did not recognize that the HCV NS3 gene product had both NTPase and helicase activity, it has already been explained on the record that this fact is not relevant to the rejected claims, which are product claims. It is well established in U.S. patent practice that discovery of a new property of a product already known in the prior art cannot serve as the basis for patentability for said known product.

3. Claims 15-22 remain allowable.

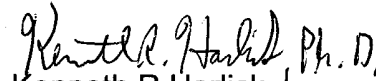
4. Houghton et al. (US 6,472,180) is made of record as a reference of interest.

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kenneth R Horlick whose telephone number is 571-272-0784. The examiner can normally be reached on Monday-Thursday 6:30AM-5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Kenneth R Horlick, Ph.D.  
Primary Examiner  
Art Unit 1637

11/08/04